

Attorney's
Docket
Number GIN-6006B4

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

METHODS AND COMPOSITIONS FOR DIAGNOSING AND TREATING PREECLAMPSIA AND GESTATIONAL TROPHOBLAST DISORDERS

the specification of which

(check one)

X is attached hereto.

_____ was filed on _____ as _____

Application Serial No. _____

and was amended on _____
(if applicable)

I do not know and do not believe that the subject matter of this application was known or used by others in the United States or patented or described in a printed publication in any country before my invention thereof, or patented or described in a printed publication in any country or in public use or on sale in the United States more than one year prior to the date of this application, or first patented or caused to be patented or made the subject of an inventor's certificate by me or my legal representatives or assigns in a country foreign to the United States prior to the date of this application on an application filed more than twelve months (six months if this application is for a design) before the filing of this application; and I acknowledge my duty to disclose information of which I am aware which is material to the examination of this application, that no application for patent or inventor's certificate on the subject matter of this application has been filed by me or my representatives or assigns in any country foreign to the United States, except those identified below, and that I have reviewed and understand the contents of the specification, including the claims as amended by any amendment referred to herein.

I acknowledge the duty to disclose to the Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

| 1. General information | | 2. Demographic data | | 3. Clinical data | | 4. Laboratory data | | 5. Treatment data | | 6. Outcome data | |
|------------------------|------------|---------------------|--------------|--------------------|----------------|--------------------|----------------|-------------------|---------------|------------------------------|-----------------------|
| Study ID | Study Name | Study Type | Study Design | Study Population | Study Location | Study Period | Study Duration | Study Funding | Study Sponsor | Study Principal Investigator | Study Co-Investigator |
| 101 | Study 1 | Phase I | Randomized | Healthy Volunteers | USA | 2010-2012 | 12 Months | \$1,000,000 | NIH | Dr. Smith | Dr. Jones |
| 102 | Study 2 | Phase II | Randomized | Cancer Patients | USA | 2013-2015 | 18 Months | \$2,500,000 | NIH | Dr. Smith | Dr. Jones |
| 103 | Study 3 | Phase III | Randomized | Cancer Patients | USA | 2016-2018 | 24 Months | \$5,000,000 | NIH | Dr. Smith | Dr. Jones |
| 104 | Study 4 | Phase IV | Randomized | Cancer Patients | USA | 2019-2021 | 30 Months | \$10,000,000 | NIH | Dr. Smith | Dr. Jones |
| 105 | Study 5 | Phase I | Randomized | Healthy Volunteers | USA | 2022-2024 | 12 Months | \$1,000,000 | NIH | Dr. Smith | Dr. Jones |
| 106 | Study 6 | Phase II | Randomized | Cancer Patients | USA | 2025-2027 | 18 Months | \$2,500,000 | NIH | Dr. Smith | Dr. Jones |
| 107 | Study 7 | Phase III | Randomized | Cancer Patients | USA | 2028-2030 | 24 Months | \$5,000,000 | NIH | Dr. Smith | Dr. Jones |
| 108 | Study 8 | Phase IV | Randomized | Cancer Patients | USA | 2031-2033 | 30 Months | \$10,000,000 | NIH | Dr. Smith | Dr. Jones |
| 109 | Study 9 | Phase I | Randomized | Healthy Volunteers | USA | 2034-2036 | 12 Months | \$1,000,000 | NIH | Dr. Smith | Dr. Jones |
| 110 | Study 10 | Phase II | Randomized | Cancer Patients | USA | 2037-2039 | 18 Months | \$2,500,000 | NIH | Dr. Smith | Dr. Jones |
| 111 | Study 11 | Phase III | Randomized | Cancer Patients | USA | 2040-2042 | 24 Months | \$5,000,000 | NIH | Dr. Smith | Dr. Jones |
| 112 | Study 12 | Phase IV | Randomized | Cancer Patients | USA | 2043-2045 | 30 Months | \$10,000,000 | NIH | Dr. Smith | Dr. Jones |
| 113 | Study 13 | Phase I | Randomized | Healthy Volunteers | USA | 2046-2048 | 12 Months | \$1,000,000 | NIH | Dr. Smith | Dr. Jones |
| 114 | Study 14 | Phase II | Randomized | Cancer Patients | USA | 2049-2051 | 18 Months | \$2,500,000 | NIH | Dr. Smith | Dr. Jones |
| 115 | Study 15 | Phase III | Randomized | Cancer Patients | USA | 2052-2054 | 24 Months | \$5,000,000 | NIH | Dr. Smith | Dr. Jones |
| 116 | Study 16 | Phase IV | Randomized | Cancer Patients | USA | 2055-2057 | 30 Months | \$10,000,000 | NIH | Dr. Smith | Dr. Jones |
| 117 | Study 17 | Phase I | Randomized | Healthy Volunteers | USA | 2058-2060 | 12 Months | \$1,000,000 | NIH | Dr. Smith | Dr. Jones |
| 118 | Study 18 | Phase II | Randomized | Cancer Patients | USA | 2061-2063 | 18 Months | \$2,500,000 | NIH | Dr. Smith | Dr. Jones |
| 119 | Study 19 | Phase III | Randomized | Cancer Patients | USA | 2064-2066 | 24 Months | \$5,000,000 | NIH | Dr. Smith | Dr. Jones |
| 120 | Study 20 | Phase IV | Randomized | Cancer Patients | USA | 2067-2069 | 30 Months | \$10,000,000 | NIH | Dr. Smith | Dr. Jones |

CLAIM OF BENEFIT OF EARLIER FOREIGN APPLICATION(S)

I hereby claim priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below, and have also identified below any foreign application(s) for patent or inventor's certificate filed by me on the same subject matter having a filing date before that of the application(s) from which priority is claimed.

Check one:

☒ no such applications have been filed.

☐ such applications have been filed as follows

EARLIEST FOREIGN APPLICATION(S), IF ANY, FILED WITHIN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

| Country | Application Number | Date of Filing (month,day,year) | Priority Claimed Under 35 USC 119 |
|---------|--------------------|------------------------------------|--|
| | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |

ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

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09902155-070904

CLAIM FOR BENEFIT OF U.S. PROVISIONAL APPLICATION(S)

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application(s) listed below.

60/216,657

(Application Serial No.)

July 7, 2000

(Filing Date)

(Application Serial No.)

(Filing Date)

(Application Serial No.)

(Filing Date)

09502535 070904

CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S)

I hereby claim the benefit under Title 35, United States Code, §120 of any earlier United States application(s) or PCT international application(s) designating the United States listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the earlier application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose to the Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date(s) of the earlier application(s) and the national or PCT international filing date of this application. As to subject matter of this application which is common to my earlier application(s), if any, described below, I do not know and do not believe that the same was known or used by others in the United States or patented or described in a printed publication in any country before my invention thereof, or patented or described in a printed publication in any country or in public use or on sale in the United States more than one year prior to the date(s) of said earlier application(s), or first patented or caused to be patented or made the subject of an inventor's certificate by me or my legal representatives or assigns in a country foreign to the United States prior to the date(s) of said earlier application(s) on an application filed more than twelve months (six months if this application is for a design) before the filing of said earlier application(s); and I acknowledge that no application for patent or inventor's certificate on said subject matter has been filed by me or my representatives or assigns in any country foreign to the United States except those identified herein.

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|-----------------------------------|------------------------|--|
| _____ (Application Serial No.) | _____ (Filing Date) | _____ (Status) (patented,pending,aband.) |
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|-----------------------------------|------------------------|--|
| _____ (Application Serial No.) | _____ (Filing Date) | _____ (Status) (patented,pending,aband.) |
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09902535 070904

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorneys and/or agents to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

| | | | |
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| Ann Lamport Hammitte | Reg. No. 34,858 | Maria C. Laccotripe | Limited Recognition |
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Direct Telephone Calls to: (name and telephone number)

Amy E. Mandragouras, Esq., (617) 227-7400

Wherefore I petition that letters patent be granted to me for the invention or discovery described and claimed in the attached specification and claims, and hereby subscribe my name to said specification and claims and to the foregoing declaration, power of attorney, and this petition.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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|--|------|
| Full name of sole or first inventor James C. Keith, Jr. | |
| Inventor's signature | Date |
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|---|------|
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|---|------|
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